EXHIBIT 2

Long-Term Follow-up of Treatment for Synthetic Mesh Complications

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Objectives: The objectives of this study are (1) to describe the presenting symptoms, findings, and treatment and (2) to describe the self-reported improvement and function at least 6 months after presentation in women presenting to 1 urogynecology division for complications associated with synthetic vaginal mesh.

Methods: Women evaluated between 2006 and 2011 were identified by diagnostic codes. We abstracted information from the medical record and attempted to contact all women to complete a follow-up telephone survey questionnaire consisting of several validated instruments.

Results: A total of 111 women were evaluated for complications associated with synthetic vaginal mesh. The mean interval from index surgery was 2.4 years. Of these, 84% were referred from outside hospitals. Index surgeries included vaginal mesh kits/vaginally placed mesh (47%), midurethral mesh slings (37%), abdominally placed vaginal mesh (11%), and vaginal mesh kit with concomitantly placed mesh sling (5%). The most common complications were extrusion (65%), contraction (17%), and chronic pelvic pain (16%). A total of 98 women underwent some type of treatment (85 surgical) by urogynecologists, pelvic pain specialists, or physical therapists. Eighty-four (76%) provided follow-up information at mean interval since presentation of 2.3 years. At follow-up, the mean (SD) Pelvic Floor Distress Inventory score was 98 (67), the mean (SD) EQ-5D index score was 0.69 (0.23), and 22% reported vaginal discharge, 15% vaginal bleeding or spotting, and 45% sexual abstinence due to problems related to mesh. A total of 71% reported being overall better, whereas 29% were the same or worse.

Conclusions: Two years after tertiary care level multidisciplinary treatment of vaginal mesh complications, many women still report symptoms that negatively impact their quality of life.

Key Words: pelvic organ prolapse, stress urinary incontinence, mesh complication, vaginal mesh

(*Female Pelvic Med Reconstr Surg* 2014;20: 126–130)

Pelvic organ prolapse (POP) and stress urinary incontinence (SUI) are common disorders in women, occurring in up to 50% and 30% of women respectively and having great impact on the quality of life.[1,2] With the primary treatment being surgery, transvaginal mesh products were introduced over the last decade with the intent of improving success rates of traditional POP and SUI repair methods, whose recurrence rates are reported as up to 30%.[2,3] Along with the increased use of vaginal mesh, there has been an increased incidence of complications unique to this repair method. A 2008 Food and Drug Administration Public Health Notification and the 2011 update described no symptomatic benefit of transvaginal mesh use but additional risks including, although not limited to, vaginal mesh exposure and contraction.[4,5] The Systematic Review Group of the Society of Gynecologic Surgeons revealed an overall mesh exposure rate of 10.3%, with a range of 0% to 29.7%.[6] The implications of mesh complications can be demonstrated by the example of 1 study where a 5-year cumulative risk of repeat surgery was found to be significantly higher for vaginal mesh repair over traditional POP repair, specifically for mesh removal/revision.[7]

To date, there are scant data about whether treatments for women with mesh complications are successful in alleviating their symptoms, especially long term. In a recent abstract, 50% of women reported persistent pain and 25% dyspareunia after treatment of mesh complications (Crosby EC, Berger MB, DeLancey JL, Fenner DE, Morgan DM. Symptom resolution after operative management of complications from vaginal mesh. Presented at the American Urogynecologic Society Annual Scientific Meeting on October 3, 2012).

Similar to other recent reports, our institution has seen an increase in volume of women referred for mesh complications over the past decade.[8] We thus undertook this project to better understand the experiences and outcomes of women referred to and treated in our clinic, with the hopes of improving our own processes related to their care. Because any synthetic mesh can cause complications after surgical implantation, we included mesh placed abdominally for POP and mesh slings placed for SUI.

The objectives of this study are (1) to describe a cohort of women presenting to our division over 6 years for complications associated with synthetic vaginal mesh and (2) to describe self-reported improvement and function at least 6 months (mean, 2.3 years) after treatment in our center.

METHODS AND MATERIALS

This study involved both retrospective chart review and follow-up survey questionnaire for women presenting for vaginal mesh complications to the Division of Urogynecology and Pelvic Reconstructive Surgery at the University of Utah between January 1, 2006 and December 31, 2011. The study protocol and instruments were reviewed by the University of Utah institutional review board, which deemed it exempt from review. We identified 221 women with 1 of the following *International Classification of Diseases, Ninth Revision* diagnostic codes: mesh erosion 939.2, mechanical complication of graft 996.39, pain due to genitourinary device/implant 996.76, infection of genitourinary device/implant/graft 996.65, unknown foreign body 939.0, mesh excision vaginal 57295, mesh excision abdominal 57296. Each medical record was reviewed, and participants were excluded

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Reprints are not available.
The authors have declared they have no conflicts of interest
This investigation was supported by the University of Utah Study Design and Biostatistics Center, with funding in part from the National Center for Research Resources, the National Center for Advancing Translational Sciences, and the National Institutes of Health, through grant 8UL1TR000105 (formerly UL1RR025764).

DOI: 10.1097/SPV.0000000000000084

whose initial surgery was something other than a vaginal mesh kit for prolapse, abdominal sacrocolpopexy with mesh for prolapse, or suburethral sling for urinary incontinence. In addition, we excluded women presenting for surgical complications due to foreign bodies other than synthetic mesh (ie, biologic allograft, xenograft, or suture), complication presentation outside the study period, or whose only complaint was surgical failure (ie, recurrent prolapse or incontinence). Electronic and paper charts of eligible women were abstracted for demographics, medical history, details of original mesh surgery, symptoms at presentation, mesh complication diagnoses, treatment modalities, and number of visits. We defined operating time as the length of the procedure in minutes.

After the chart review, we performed a follow-up survey questionnaire. We mailed each patient a letter describing our follow-up project and allowing each to opt out. The letter stated our intent to contact the patient by telephone to ask questions about her progress since her last visit with us. Women were also given an option to respond by written questionnaire. The conducted survey included 44 questions, 3 regarding follow-up treatment since last visit; 20 questions from the Pelvic Floor Distress Inventory (PFDI-20) short form; 4 additional questions addressing vaginal discharge, spotting, and sexual activity; 7 questions modified from the Pelvic Floor Impact Questionnaire (PFIQ) short form by changing the stem to, "In the past 3 months, have problems related to your mesh surgery affected your:…" and by reporting answers on a scale of 0 to 100 (0 correlating with "not at all" affected and 100 representing "greatly" affected).[9] Thus, higher PFIQ scores correspond to greater dysfunction. We also included 5 health status questions from EQ-5D; these refer to "your health today" using 5 domains (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), with 3 response options (no problems, moderate problems, severe problems).[10] In addition, we used a modified EQ-VAS (verbally reported scale instead of visual analog) prompting for overall health state on a scale of 0 to 100, where 0 represents the "worst possible health state" and 100 represents the "best possible health state." We included 2 multiple-choice questions regarding overall improvement since the treatment at our institution and satisfaction with the clinic experience. In addition, women responded to several open-ended questions about their experience; these are addressed in the companion paper.[11]

This is a descriptive study; results are presented in aggregate form and by mesh type, and the sample size is insufficient to allow comparisons between groups. The PFDI answers were scored in the usual fashion to give a total score with possible results ranging from 0 to 300, the higher number representing greater dysfunction. The PFIQ short form answers were resulted as medians with interquartile ranges. EQ-5D results were calculated in 2 forms, first as a simple aggregate of "any reported problem" and second as a scored index. To calculate the overall EQ-5D index, we applied the scoring algorithm for the US general population as described by Shaw et al via the Microsoft Excel calculator provided by the Agency for Healthcare Research and Quality.[12,13]

RESULTS

One hundred eleven women met the inclusion criteria and are the subject of our study. Of these, 16 women (14%) had complications from within our hospital system (none of which included vaginally placed mesh for POP), and 93 (83.7%) were referred from outside hospitals, with 2 unknown/unstated referral sources. In women presented after procedures performed at nearly 20 different surgical facilities, 79 (71%) occurring within the state of Utah, 31 (28%) from 8 outside states, and 1 unknown. Eighty women (72%) were referred by a source other than the original surgeon (ie, women were referred by friends, other physicians or clinicians, or self-referred). Table 1 summarizes the study population characteristics. The mean interval from the placement of mesh to the presentation at our institution was 2.4 years (range, 7 days to 16.3 years). We were able to obtain and review operative reports of the index mesh

TABLE 1. Participant Characteristics

Age, mean (SD), y	54.6 (13.1)
BMI, mean (SD), kg/m^2	28.1 (5.5)
Parity, mean (SD)	3.2 (2.0)
Race, n (%)	
White	79 (67)
Hispanic	4 (3.6)
Asian	1 (0.9)
Unknown/not recorded	32 (28.8)
Marital Status, n (%)	
Married	86 (77.5)
Divorced	14 (12.6)
Widowed	6 (5.4)
Single	4 (3.6)
Unknown/not recorded	1 (0.9)
Insurance, n (%)	
Private	69 (62.2)
Public	36 (32.4)
None	4 (3.6)
Unknown	2 (1.8)
Tobacco use, n (%)	
Current use	19 (17.1)
None	92 (82.9)
Medical comorbidities, n (%)	
Depression/anxiety	32 (28.8)
Fibromyalgia/chronic pain	21 (18.9)
Diabetes	12 (10.8)
None	47 (42.3)
Medication use, n (%)	
Pain medication	45 (40.5)
Antidepressant	36 (32.4)
Hormone	33 (29.7)
Anxiolytic	22 (19.8)
Neuromodulator	16 (14.4)
Insulin/oral antiglycemic	12 (10.8)
Steroid	1 (0.9)
None	33 (29.7)
Prior pelvic surgery, n (%)*	
Hysterectomy	57 (51.4)
Cesarean	16 (14.4)
POP	25 (22.5)
No mesh	20
With mesh	5
SUI	10 (9)
No mesh	7
With mesh	3

*Before index surgery leading to complication.

Pain medication indicates NSAID or narcotic; BMI, body mass index.

surgery for 104 women (94%). Fifty women (45%) had undergone intervention before presentation at our institution, 34 (68%) of which included excision of mesh. Of the 111 women seen for mesh complications, 52 were following vaginal mesh kits or vaginally placed mesh, 42 had complications from midurethral mesh slings (of these, 7 were from mini-slings), 12 from abdominally placed vaginal mesh, and 5 from both a vaginal mesh kit and from a concomitantly placed mesh sling. Among complications, there were 7 different marketed mesh kit products represented (9 anterior only, 6 posterior only, 2 anterior and posterior, and 33 total or apical), 12 different midurethral sling products, and 3 different synthetic mesh grafts for abdominally placed vaginal mesh. Thirty-two patients had additional mesh products placed at the time of the index surgery that on evaluation were not contributing to patient symptoms—26 of 52 women (50%) with complications from vaginally placed mesh had also undergone simultaneous placement of a mesh sling, which was found to be uncomplicated; 4 of 42 women (9.5%) with complications from mesh slings also had uncomplicated vaginally placed mesh in place; and 2 of 12 women (16.7%) with abdominally placed mesh had uncomplicated mesh slings in place.

The most common symptoms at presentation to our clinic were pain (77/111, 69%), dyspareunia (55/111, 49.5%), vaginal discharge (31/111, 27.9%), and vaginal bleeding (23/111, 20.7%).

After evaluation, we identified 72 women (64.9%) with vaginal mesh extrusion, 19 (17.1%) with mesh contraction, 18 (16.2%) with chronic pelvic pain, 10 (9%) with obstructive voiding, and 4 women (3.6%) with mesh erosions into bladder/bowel (please note that diagnoses are not exclusive).

The most common site of mesh extrusion was the anterior vaginal wall (n = 32) followed by the vaginal apex (n = 23), midurethra (n = 15), and posterior vagina (n = 12), with 10 of these representing multiple sites of mesh extrusion in the same patient (8 women with 2 sites of mesh extrusion and 1 patient with 3 sites of extrusion).

After evaluating these 111 women, 13 received no intervention by our physicians due to recommendations for watchful waiting (2), referral to other specialist (2), lost to follow-up (1), or second opinion only/referred back to index surgeon/lack of insurance compatibility (8). Among the 98 women receiving intervention, the mean number of visits to our institution was 5.8 (range, 2–30). Eighty-five women (86.7%) underwent mesh excision, 82 ultimately in the operating room and 3 exclusively in the clinic. The mean (SD) number of excisions was 1.2 (0.5), and the mean (SD) operative length for the first excision was 86.0 (49) minutes (range, 12–259 minutes). An additional 13 women underwent second mesh excision with mean (SD) operative length of 94.9 (75) minutes (range, 12–248 minutes), and 3 of those women underwent third excision with mean (SD) operative length of 88.8 (24) minutes (range, 103–146 minutes). Perioperative complications were rare and included 2 intraoperative consultations, 1 with general surgery for resection of appendix adherent to mesh in a patient with erosion after an abdominal sacrocolpopexy and a consultation with colorectal surgery for colonoscopy to evaluate for mesh erosion. In addition to surgical treatment, 31 women (31.6%) received vaginal estrogen, 10 women (10%) received trigger point injections, and 9 (9.2%) received oral neuromodulators. Ten women (10%) were evaluated and treated by our pelvic pain specialist, and 12 (12.2%) were referred for physical therapy.

After medical record review, we attempted to contact the 111 women for our follow-up questionnaire. Contact information was incorrect or outdated for 10, 1 woman was excluded because of language barrier, 1 woman was deceased, and 11 women did not respond to contact attempts. Thus, we were able to contact 88 women. Of these, 5 requested the mail-in paper survey (and 2 returned it), and 1 of these subsequently declined participation. Thus 84 of 111 (76.1%) ultimately provided follow-up data; 1 woman opted to only answer 1 of the open-ended qualitative questions, and 1 woman omitted the PFIQ and EQ-5D.

The mean time from initial presentation to our clinic to follow-up survey was 2.3 years (range, 209 days to 6.5 years). Since their last visit with our clinic, 15 women had received additional treatment elsewhere for mesh-related problems (physical therapy, n = 6; surgical excision, n = 5; medical therapy, n = 3; other, n = 3), 8 were treated for POP (physical therapy, n = 4; surgical treatment, n = 4), and 5 for SUI (physical therapy, n = 1; surgical treatment, n = 2; medical therapy, n = 3).

The mean (SD) overall PFDI score at follow-up was 98 (67) of 300. The mean (SD) PFDI scores were 112.5 (74) for women seen for complications of transvaginally placed mesh alone, 96.8 (61) for mesh sling alone, 59.1 (31) for transabdominally placed mesh, and 58.4 (70) for transvaginal mesh with mesh sling. Forty-four women (54%) reported pain or discomfort in the lower abdominal/genital region (affirmative response to PFDI question, "Do you usually experience pain or discomfort in the lower abdomen or genital region?"). The PFDI subscale scores are summarized in Table 2.

Vaginal discharge was reported by 22% (n = 18) of women, most frequently described as "somewhat bothersome" on a 4-point scale (not at all bothersome, somewhat bothersome, moderately, or quite a bit bothersome). Vaginal bleeding or spotting was reported in 14.6% (n = 12) at follow-up, most frequently reported as "quite a bit bothersome" on the same 4-point scale.

Forty women (48%) at follow-up reported being currently sexually active; of these, 21 reported the need to abstain from intercourse from some period because of mesh-related problems since initial surgery. Of those not sexually active (n = 42), 19 (45%) reported abstinence due to problems related to mesh. Of

TABLE 2. Pelvic Floor Distress Inventory Scores at Follow-up

		Complication Attributed to:			
	Entire Population	**Transvaginal Mesh**	**Sling**	**Transabdominal Mesh**	**Transvaginal Mesh + Sling**
PFDI total*	98 (67)	112.5 (74)	96.8 (61)	59.1 (31)	58.4 (70)
POPDI	29.4 (29)	35.6 (34)	28.4 (25)	9.6 (7)	20.8 (22)
CRADI	27.5 (24)	31.2 (25)	25.8 (24)	23.2 (19)	12.5 (21)
UDI	36.6 (28)	37.5 (30)	43.1 (27)	26.3 (23)	10 (8)

*Scores reflect mean (SD).

POPDI indicates POP Distress Inventory; CRADI, Colorectal-Anal Distress Inventory; UDI, Urinary Distress Inventory.

TABLE 3. Modified Pelvic Floor Impact Questionnaire Short Form Results at Follow-up

In the Past 3 Months, Have Problems Related to Your Mesh Surgery Affected Your:	Complication Attributed to:				
	Entire Population	Transvaginal Mesh	Sling	Transabdominal Mesh	Transvaginal Mesh + Sling
1. Ability to do household chores	20 (0–50)	22.5 (0–52.5)	10 (0–55)	10 (0–23.8)	26 (1.5–56.3)
2. Physical recreation	35 (0–75)	32.5 (0–70)	40 (0–77.5)	17.5 (0–66.3)	38.5 (1.5–75)
3. Entertainment activities	1 (0–55)	0.5 (0–67.8)	20 (0–55)	0 (0–0)	37.5 (19.3–62.5)
4. Ability to travel by car or bus more than 30 minutes from home	6 (0–60)	12.5 (0–70)	15.5 (0–50)	0 (0–0)	26 (1.5–57.5)
5. Participating in social activities outside your home	10 (0–60)	15 (0–70)	10 (0–65)	0 (0–0.75)	32.5 (19.3–55)
6. Emotional health	50 (0–80)	45 (0–80)	50 (0–87.5)	1.5 (0–43.8)	40 (27.5–50)
7. Feeling frustrated	60 (0–81)	60 (21.3–82)	80 (0–95)	4 (0–43.8)	45 (35–50)

*Results are reported as median (Quartile 1–Quartile 3).

currently sexually active women, 31 (77.5%) reported sexual activity that is at least somewhat enjoyable, 24 (60%) reported some amount of pain, and 5 (12.5%) reported that their partner noted pain during intercourse.

Results of the modified PFIQ short form at follow-up are shown in Table 3. Notably, the highest scores reflecting continued problems felt to be related to mesh were reported in the following areas: "feeling frustrated" (median score, 60) and "emotional health" (median score, 50). Results of patient-reported overall health status as assessed by the EQ-5D are shown in Figure 1. The mean (SD) EQ-5D index score was 0.69 (0.23). The mean (SD) EQ-VAS at follow-up (scale, 0–100) was 62.7 (24.5).

Of the 82 respondents, 71% reported being overall better at follow-up than before being seen and treated in our clinic (26.8% were "better," 18.3% "much better," and 25.6% "very much better"), whereas 29% reported being the same or worse than they were before being seen in our clinic (13.4% the "same," 9.8% "worse," 3.7% "much worse," and 2.4% "very much worse") (Fig. 2). Similar trends were seen for the 15 women whose index surgery consisted of solely a suburethral sling, with no concomitant procedures. Of the 10 that underwent sling lysis, 6 were available for follow-up; of these, 1 reported being very much worse, 1 much worse, 1 much better, and 3 very much better. Three of the 5 that underwent mesh excision for extrusion were available for follow-up; of these, 1 reported being about the same, 1 better, and 1 much better.

Finally, of the women surveyed, 88% were satisfied with their overall clinic experience at our institution (35% "extremely satisfied," 38% "very satisfied," 15% "satisfied," 9% "somewhat satisfied," 2% "dissatisfied," 1% "very dissatisfied," and 0% "extremely dissatisfied").

DISCUSSION

Similar to other reports, the most common mesh complications reported in our study were vaginal mesh extrusion and mesh contraction, with subsequent presenting symptoms of pelvic pain, vaginal discharge, and vaginal bleeding.[6,14]

Vaginal mesh placement for POP and SUI continues to put women at risk for complications that can be life altering. In our experience, the treatment of mesh complications requires a significant investment in the form of clinic visits, surgical time, use of additional resources, and intervention before referral (45%). However, after our best efforts at treatment, many women continue to report problems related to mesh placement. We found that mesh complications are difficult to treat successfully, with the majority requiring surgical intervention and multiple visits and nearly 20% of those requiring additional excision. This information can be useful in counseling women regarding the risks and expectations of the treatment of mesh complications.

Two years after treatment (4.5 years after the index mesh surgery), women continue to report symptoms that negatively impact their quality of life. It is also important to note the impact of mesh complications on emotional health. At follow-up, the highest PFIQ scores overall (higher scores corresponding to greater dysfunction) were reported in regards to mesh complications that contributed to emotional health and caused feelings of frustration. Furthermore, the mean EQ-5D index score of

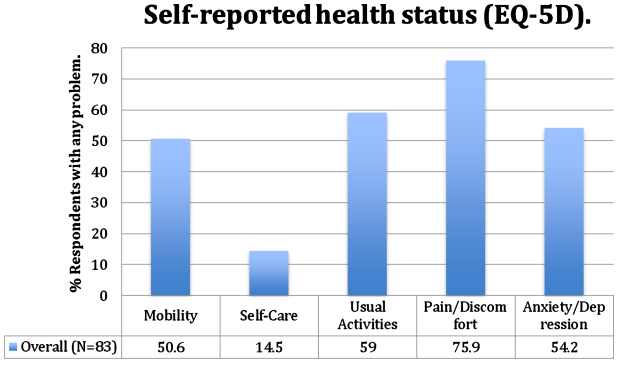

FIGURE 1. Self-reported health status (EQ-5D).

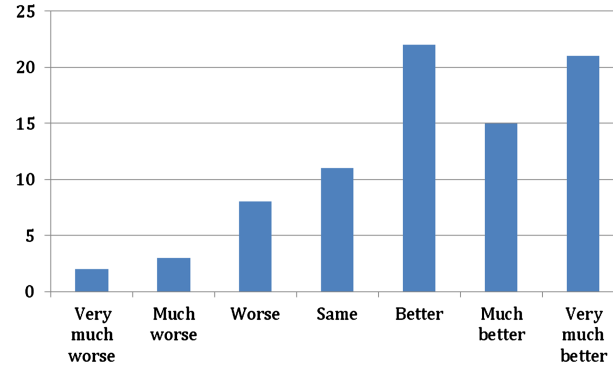

FIGURE 2. Self-reported improvement at follow-up.

0.69 in our study population was generally lower than the US general population norm for women of similar ages, where average indices ranged from 0.84 to 0.89 in US women ages 35 to 64.[15] Similarly, compared with the self-reported health status means of a general population of middle-aged women, EQ-VAS scores from our study at follow-up were also lower, averaging 62.7 compared with reported normal ranges of 80.26 to 86.35.[16]

The number of women referred for complications increased each year of the study period, with 49 women (44%) referred to our clinic during 2011, the final year of our data collection period. Given that the average time between mesh placement and presentation to our clinic was 29 months, this seems to correlate with a continued or increased use of vaginal mesh despite Food and Drug Administration warnings made in October 2008 and July 2011.[4,5] This trend is continuing beyond our study period, as our group saw 136 women with mesh complications in 2012. Similar to other reports, fewer than 25% of women were referred by the surgeon that placed their mesh.[17,18] This may contribute to the continued use of these products, as the physicians placing them may not be fully aware of their own mesh complications.

Although the literature is replete with studies describing the incidence of mesh complications, or how such complications were treated, our study provides new information about how women fare long term after being treated for complications related to mesh placement.[8,14,18–21] Other strengths of our study include the high response rate (84% of women for whom we had correct contact information) and the use of validated instruments to assess various domains of patient-reported outcomes. However, we did not validate the PFIQ after changing the stem to reflect problems related to mesh surgery from the original stem assessing how pelvic floor symptoms impacted various activities.

Although our case series is 1 of the larger ones addressing treatment of mesh complications published to date, we do not have sufficient power to compare outcomes by surgical types. We also excluded complications from nonsynthetic vaginal mesh products, but we recognize unique complications from other types of grafts as well.

In conclusion, our findings demonstrate the impact of vaginal mesh complications on long-term quality of life measures and symptoms. Although women reported high rates of satisfaction with our clinic, this study suggests that there is much room for improvement. We suspect that many more women in our care would benefit from evaluations by other specialists (such as physical therapists, pelvic pain specialists, and mental health specialists), but we were constrained by the long distances many women travel to our clinic, the unavailability of such specialists on the same day as the appointment with us or in their home location, and by insurance plans that covered only specific urogynecologic care. The results of this study, in combination with those gleaned from our qualitative companion manuscript, highlight the need for new multidisciplinary, yet efficient, approaches to managing women with mesh complications. In particular, when feasible, periodic follow-up visits over many years may shed light on previously unreported or new symptoms such that treatment may be offered.

REFERENCES

1. Maher C, Feiner B, Baessler K, et al. Surgical management of pelvic organ prolapse in women. *Cochrane Database Syst Rev* 2013;4:CD004014.
2. Ogah J, Cody DJ, Rogerson L. Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women: a short version Cochrane review. *Neurourol Urodyn* 2011;30(3):284–291.
3. Olsen AL, Smith VJ, Bergstrom JO, et al. Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. *Obstet Gynecol* 1997;89(4):501–506.
4. Food and Drug Administration. *FDA Public Health Notification: Serious Complications Associated With Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence*. Silver Spring, MD: FDA; 2008. Available at: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm061976.htm. Accessed August 28, 2013.
5. Food and Drug Administration. *FDA Safety Communication: UPDATE on Serious Complications Associated With Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse*. Silver Spring, MD: FDA; 2011. Available at: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm. Accessed August 28, 2013.
6. Abed H, Rahn DD, Lowenstein L, et al. Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review. *Int Urogynecol J* 2011;22(7):789–798.
7. Jonsson Funk M, Visco AG, Weidner AC, et al. Long-term outcomes of vaginal mesh versus native tissue repair for anterior vaginal wall prolapse. *Int Urogynecol J* 2013;24:1279–1285.
8. Lee D, Dillon B, Lemack G, et al. Transvaginal mesh kits—how "serious" are the complications and are they reversible? *Urology* 2013;81(1):43–48.
9. Barber MD, Walters MD, Bump RC. Shortforms of two condition-specific quality-of-life questionnaires for women with pelvic floor disorders (PFDI-20 and PFIQ-7). *Am J Obstet Gynecol* 2005;193:103–113.
10. The EuroQol Group. EuroQol—a new facility for the measurement of health-related quality of life. *Health Policy* 1990;16(3):199–208.
11. Dunn GE, Hansen BL, Egger MJ, et al. Changed women: the long-term impact of vaginal mesh complications. *Fem Pelvic Med* 2014.
12. Shaw JW, Johnson JA, Coons SJ. US valuation of the EQ-5D health states: development and testing of the D1 valuation model. *Med Care* 2005;43(3):203–220.
13. Calculating the U.S. Population-Based EQ-5D™ Index Score. August 2005. Agency for Healthcare Research and Quality, Rockville, MD. Available at: http://www.ahrq.gov/rice/EQ5Dscore.htm. Accessed August 28, 2013.
14. Kirby AC, Nager CW. Indications, contraindications, and complications of mesh in the surgical treatment of urinary incontinence. *Clin Obstet Gynecol* 2013;56(2):257–275.
15. Fryback DG, Dunham NC, Palta M, et al. US norms for six generic health-related quality-of-life indexes from the National Health Measurement study. *Med Care* 2007;45(12):1162–1170.
16. Kind P, Hardman G, Macran S. *UK Population Norms for EQ-5D. University of York Centre for Health Economics Discussion Paper 172*. 1999. Available at: http://www.york.ac.uk/media/che/documents/papers/discussionpapers/CHE%20Discussion%20Paper%20172.pdf. Accessed January 28, 2014.
17. Rostaminia G, Shobeiri A, Quiroz LH, et al. Referral pattern for vaginal mesh and graft complications to the University of Oklahoma Pelvic and Bladder Health Clinic. *J Okla State Med Assoc* 2012;105(9):356–358.
18. Blaivas JG, Purohit RS, Weinberger JM, et al. Salvage surgery after failed treatment of synthetic mesh sling complications. *J Urol* 2013;190:1281–1286.
19. Nguyen JN, Jakus-Waldman SM, Walter AJ, et al. Perioperative complications and reoperations after incontinence and prolapse surgeries using prosthetic implants. *Obstet Gynecol* 2012;119(3):539–546.
20. Chermansky CJ, Winters JC. Complications of vaginal mesh surgery. *Curr Opin Urol* 2012;22(4):287–291.
21. El-Nashar SA, Kim-Fine S, Trabuco EC. Early and complete excision of vaginally placed synthetic mesh. *Female Pelvic Med Reconstr Surg* 2013;19(3):186–187.